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TECH CENTER 1600/2900

In re PATENT APPLICATION of:

Akintade Oyedele Dare.

Serial No.: 09/741,426

Group Art Unit: 1634

Filed: December 21, 2000

Examiners: Goldberg

For: Method and Kit for Quantitating
Genomic DNA Damage and Repair
Capacity

January 7, 2002

AMENDMENT AFTER FINAL

Commissioner of Patent
and Trademarks
Washington, D.C. 20231

Sir:

In reply to the Office Action mailed December 3, 2002, applicant request
reconsideration.

In the Specification

Please enter the attached substitute page 9 into the specification. A red-line version is
attached.

In the Claims

Please enter the following substitute claim 5 in the application. A red-line version is
attached.

5. (Twice Amended) The method as recited in claim 1, wherein the surface treatment
solution used in the mixing step comprises one of Reacti-bind and Protamine
Sulphate.

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REMARKS

By the above amendment to the specification, applicant has removed the embedded hyperlink at page 9.

Applicant has also corrected the spelling of "Protomine" in claim 5.. appreciates the examiner's thorough examination of the application, as reflected by the rather extensive action. Applicant has also made proper use of trademark Protomine Sulfate and Reacti-bind in his specification.

Applicant appreciates the examiner's accordance of the priority date of December 21, 1999 to show providing a "mixture" of DNA and Reacti-bind. It should be noted, however, that the mixture as provided by certain claims, may occur before, during, or after providing DNA on the analysis plate – not just "prior to contacting" as the examiner states.

The examiner has rejected all claims as being unpatentable under §103(a) over certain references in view of Pierce Instructions (Product Description Number 17250, July 1999). In light of applicant's earlier research and his prior communications with Pierce about certain aspects of his invention, applicant swears behind the July 1999 Pierce publication by setting forth in the attached declaration facts and documents substantiating his conception and reduction to practice before July 1999. Applicant also sets forth his earlier contacts with Pierce.

Reconsideration is respectfully requested.

Respectfully submitted,



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Redline Claims
Serial No. 09/741,426

5. (Twice Amended) The method as recited in claim 1, wherein the surface treatment solution used in the mixing step comprises one of Reacti-bind and [Protomine] Protamine Sulphate.

oxidative damage. The number of AP sites is quantified by measuring HRP chromogenic substance by an ELISA method.

5 Alternatively, the sample and control DNA may be tagged or labeled separately with a biotin residue of the ARP reagent, and then bound to the analysis plate for comparison. That is to say, for example, a method of the invention may be practiced by reacting ARP with AP sites of DNA of cells in culture before binding the DNA to the analysis plate since ARP is selectively permeable to cell membranes. Once sample DNA and control DNA are tagged
10 while in culture, they are then extracted, isolated, purified, and bound to the plate for further analysis in accordance with the embodiments described herein. This "in culture" ARP reaction provides even greater sensitivity in detecting abasic sites because background noise is completely removed before other steps of the methods even begin.

15 The assay method described herein provides an accurate, rapid and cost-effective way to count abasic (AP) sites and DNA (deoxyribose nucleic acid) base modifications in genomic DNA of cells and tissues. Measurements are performed directly, rather than indirectly, and are performed completely on an analysis plate, such as a commercially available microtiter plate, without the need
20 to remove and/or transport samples to other laboratory facilities. Once DNA samples are purified, an assay may be completed within a few hours using methods and apparatuses of the present invention. Apart from the description contained herein, certain aspects of the invention claimed hereby may be found in recent publications predicated on research of the inventor hereof, including
25 Dojindo Newsletter Vol. 2, entitled Oxidative Stress, DNA Damage and Human Diseases published in the year 2000 by Dojindo Molecular Technologies of Gaithersburg, Maryland, and Technical Manual: DNA Damage Quantification Kit - AP Site Counting, Dojindo Product Code AK02-12, also found at
30 www.dojindo.com, each of which are incorporated herein by reference.

oxidative damage. The number of AP sites is quantified by measuring HRP chromogenic substance by an ELISA method.

Alternatively, the sample and control DNA may be tagged or labeled separately with a biotin residue of the ARP reagent, and then bound to the analysis plate for comparison. That is to say, for example, a method of the invention may be practiced by reacting ARP with AP sites of DNA of cells in culture before binding the DNA to the analysis plate since ARP is selectively permeable to cell membranes. Once sample DNA and control DNA are tagged while in culture, they are then extracted, isolated, purified, and bound to the plate for further analysis in accordance with the embodiments described herein. This "in culture" ARP reaction provides even greater sensitivity in detecting abasic sites because background noise is completely removed before other steps of the methods even begin.

The assay method described herein provides an accurate, rapid and cost-effective way to count abasic (AP) sites and DNA (deoxyribose nucleate acid) base modifications in genomic DNA of cells and tissues. Measurements are performed directly, rather than indirectly, and are performed completely on an analysis plate, such as a commercially available microtiter plate, without the need to remove and/or transport samples to other laboratory facilities. Once DNA samples are purified, an assay may be completed within a few hours using methods and apparatuses of the present invention. Apart from the description contained herein, certain aspects of the invention claimed hereby may be found in recent publications predicated on research of the inventor hereof, including Dojindo Newsletter Vol. 2, entitled Oxidative Stress, DNA Damage and Human Diseases published at www.dojindo.com/newsletter/review_vol2.html in the year 2000 by Dojindo Molecular Technologies of Gaithersburg, Maryland, and Technical Manual: DNA Damage Quantification Kit - AP Site Counting, Dojindo Product Code AK02-12, also found at www.dojindo.com, each of which are incorporated herein by reference.